BB. COUNT TWENTY NINTH

Violations of the Maryland FCA by Defendants

296. Defendants violated the Maryland Health False Claims ACT, as amended by Maryland Laws Ch 66. Title 2, Subchapter 6, § 2-601 to § 2-610 ("Maryland FCA") in the following respects:

a. Defendants violated the Maryland FCA by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

b. Defendants violated the Maryland FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

c. Defendants violated the Maryland FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;

d. Defendants violated the Maryland FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

CC. COUNT THIRTIETH

Violations of the Washington FCA by Defendants

297. Defendants violated the Washington Medicaid Fraud False Claims Act, WASH. SESS. LAWS, LAWS OF 2012, ch. 241 §§ 201 through 214 ("Washington FCA") in the following respects:

a. Defendants violated the Washington FCA, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

b. Defendants violated the Washington FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

c. Defendants violated the Washington FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;

d. Defendants violated the Washington FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

DD. COUNT THIRTY FIRST

Violations of the Colorado FCA by Defendants

298. Defendants violated the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310 ("Colorado FCA") in the following respects:

a. Defendants violated, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

b. Defendants violated the Colorado FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

c. Defendants violated Colorado FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;

d. Defendants violated Colorado FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

EE. COUNT THIRTY SECOND

Violations of the Iowa FCA by Defendants

299. Defendants violated the Iowa False Claims Act ("Iowa FCA") Iowa Code §§ 685.1 through 685.7 in the following respects:

a. Defendants violated Iowa FCA, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

b. Defendants violated the Iowa FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

c. Defendants violated Iowa FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;

d. Defendants violated the Iowa FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

FF. COUNT THIRTY THIRD

Pratta, individually under the under the New Jersey Conscientious Employee Protection Act N. J. Stat. Ann. § 34:19-1 et. seq. ("CEPA") v Defendants.

300. All of the allegations set forth herein in paragraphs 1 - 265 are incorporated herein by reference as if fully set forth at length.

301. Pratta had a reasonable and good faith belief that the actions described herein, specifically in ¶ 104 to ¶ 228 and ¶ 232 to ¶ 255 in were illegal and/or violative of a law, rule or regulation. As an example, Pratta became aware and observed numerous serious compliance issues and concerns relating to Patrick Sullivan and others, including, inter alia, Report Number MLCK-16-12-002, (*violation of policy prohibiting sales representative from being with head pharmacist of medical facility*) all of which she reported in August 2016 to Angie Woods, HR Director.

302. Pratta's disclosures to her supervisory personnel of the policies described herein and refusal to participate in the activities, policies or practices of Defendant which she felt were fraudulent and violative of law and/or criminal were protected pursuant to the provisions of N.J.S.A. 34:19-3(a) and (c)(1), (2) and (3).

303. The actions of Defendant in terminating the employment of Pratta and otherwise adversely affecting Pratta's employment as set fort herein were in retaliation for Pratta's complaints and objections and/or refusal to participate in activities, polices and practices of Defendant which Pratta reasonably believed to be fraudulent and violative of law and/or criminal, which have been set forth at length herein.

304. In order to succeed on a claim under the New Jersey Conscientious Employee Protection Act ("CEPA"), N.J.S.A. 34:19-1, et seq., and more specifically, 34:19-3(a) and/or ©, a Plaintiff must show the following

(i) she *reasonably believed* that an activity, policy or practice of her employer was in violation of a law, rule or regulation promulgated pursuant to law, or was fraudulent or criminal, or was incompatible with a clear mandate of public policy concerning the public health, safety, or welfare or protection of the environment.

(ii) she objected to, complained about, or refused to participate in, the activity, policy or practice; or reported the wrong doing to an appropriate enforcement authority

(iii) retaliatory action was taken against her (i.e., an adverse employment action occurred); and

(iv) there was a causal connection between the Plaintiff's action and the retaliatory or adverse action of the employer.

305. Pratta went on disability January 11,2016 until June 2th 2016 and then again went out again on December 20,2016 as a result of knee surgeries.

306. Shortly thereafter, Pratta was terminated because she was allegedly a "low performer" based on the result of a company wide review to reduce the neurology sales force based on performance. Out of 84 neurology sales representatives, 7 were laid off which presumably represented the bottom tier of those representatives who did not achieve their respective goals, claiming that she only met 47.8% of her goal during this period and, based on her comparable results with others, her position was selected for termination. The selected period of review were the five quarters beginning with the last two quarters of 2015 and the first three quarters of 2016.

307. Even though she was on medical leave, Pratta followed through on all her referrals and her offices. Based on the 5 quarters that were used in the analysis, Pratta was at 58.1% to goal. Despite the fact that Ms Pratta provided objective quantifiable evidence that the company's calculations were in error and that she had achieved 58.1% of her goal, placing her at 59 out of 84 in terms of performance, Company refused to re-consider it's decision to terminate her employment.

WHEREFORE, the Pratta demands judgment against Defendant for:

(a) Any and all remedies available under the New Jersey CEPA;

(b) An Award of compensatory damages for injuries including emotional distress and physical anguish, suffered as a result of Defendant's violations of a New Jersey law against discrimination;

(c) Punitive damages;

(d) Attorney's fees and costs incurred by the need to bring this litigation pursuant to the fee shifting provisions of the New Jersey CEPA;

(e) Pre and post judgment interest;

(f) Any and all damages actually incurred by plaintiff, including actual, consequential and special damages; and

(g) Such other relief as the Court may deem equitable and just.

GG. COUNT THIRTY FOURTH

Pratta, individually under the under the New Jersey Law Against Discrimination Act N. J. Stat. Ann. N.J.S.A. 10:5-12 ("LAD") v Defendants

308. All of the allegations set forth herein in paragraphs 1 - 307 are incorporated herein by reference as if fully set forth at length.

309. Pratta went on disability January 11,2016 until June 2th 2016 and then again went out again on December 20,2016 as a result of knee surgeries. As a result she was disabled.

310. Pratta became aware and observed numerous serious compliance issues and concerns relating to Patrick Sullivan and others, including, inter alia, harassment regarding her disability and Report Number MLCK-16-12-002, (*violation of policy prohibiting sales representative from being with head*

pharmacist of medical facility) all of which she reported in August 2016 to Angie Woods, HR Director.

311. Pratta's disclosures that she was being discriminated against as result of her disability violates the LAD which makes it unlawful to subject people to differential treatment based on inter alia,race, creed, color, national origin, nationality, ancestry, age, sex (including pregnancy), familial status, marital status, domestic partnership or civil union status, and disability.

312. Shortly thereafter, Pratta was terminated because she was allegedly a "low performer" based on the result of a company wide review to reduce the neurology sales force based on performance.

WHEREFORE, the Pratta demands judgment against Defendant for:

(a) Any and all remedies available under the New Jersey LAD;

(b) An Award of compensatory damages for injuries including emotional distress and physical anguish, suffered as a result of Defendant's violations of the LAD;

© Punitive damages;

(d) Attorney's fees and costs incurred by the need to bring this litigation pursuant to the fee shifting provisions of the New Jersey law against discrimination;

(e) Pre and post judgment interest;

(f) Any and all damages actually incurred by plaintiff, including actual, consequential and special damages; and

(g) Such other relief as the Court may deem equitable and just.

XIV. DAMAGES

313. The measure of damages the United States is entitled to recover under the FCA is the amount of money the government paid out by reason of the false claims over and above what it would have paid out if the claims had not been false or fraudulent. *Marcus,* 317 U.S. at 543-545, 63 S.Ct. 379; *United States v. Neifert-White,* 390 U.S. at 232, 88 S.Ct. 959. The government is allowed to recover three times the amount of its damages. 31 U.S.C. § 3729(a). "FCA damages 'typically are liberally calculated to ensure that they afford the government complete indemnity for the injuries done it.' " *United States ex rel. Roby v. Boeing Co.,* 302 F.3d 637, 646 (6th Cir.2002) (quoting *United States ex rel. Compton v. Midwest Specialties, Inc.,* 142 F.3d 296, 304 (6th Cir.1998)).

314. The computation of damages does not have to be done with mathematical precision but, rather, may be based upon a reasonable estimate of the loss.

315. The government is entitled to recover a civil penalty for each false claim. Each knowing submission of a false or fraudulent claim is a separate violation of the False Claims Act. 31 U.S.C. § 3729(a)(2). Thus, the number of violations of the False Claims Act depends on the number of false or fraudulent

claims or other requests for payments that defendant caused to be submitted. A penalty is assessed per false claim. *See United States v. Bornstein,* 423 U.S. 303, 313, 96 S.Ct. 523, 46 L.Ed.2d 514 (1976); *United States v. Killough,* 848 F.2d 1523, 1533 (11th Cir.1988) (holding that each separate fraudulent submission by a defendant demanding payment by the government.

316. The penalty is mandatory. See United States v. Hughes, 585 F.2d 284, 286 (7th Cir.1978); *Killough,* 848 F.2d at 1533-34. As the legislative history to the 1986 Amendments to the FCA explains:

> The imposition of this forfeiture is automatic and mandatory for each claim which is found to be false. The United States is entitled to recover such forfeiture solely upon proof that false claims were made, without proof of any damages.... A forfeiture may be recovered from one who submits a false claim even though no payments were made on the claim. S.Rep. No. 345, 99th Cong., 2d Sess. at 8 (July 28, 1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5273 (internal citation omitted).

317. The United States does not need to prove actual damages in order to recover these statutory penalties. The United States may recover penalties upon a showing that the claims were false, even if no damage is proved. *Varljen v. Cleveland Gear Co., Inc.,* 250 F.3d 426, 429 (6th Cir.2001) ("recovery under the FCA is not dependent upon the Government's sustaining monetary damages"); *see also United States ex rel. Hagood v. Sonoma County Water Agency,* 929 F.2d 1416, 1421 (9th Cir.1991) ("No damages need be shown in order to recover the penalty") (citing *721 *Rex Trailer Co. v. United States,* 350 U.S. 148, 153 n. 5, 76 S.Ct. 219, 100 L.Ed. 149 (1956).

XV. RELIEF REQUESTED

318. Relator requests the following relief be imposed against Defendants:

(a) That the United States be awarded three times the amount of damages which it sustained because of the acts of Defendants pursuant to §3729(a)(1)(2) and (3) of the FCA;

(b) That Defendants each be held liable for civil penalties of up to $21,563.00, but not less than $10,781.00 (as adjusted pursuant to §3729 of the FCA and the Civil Penalties Act), to the U.S. for each and every act in violation of the FCA; that the Defendants each be held liable for civil penalties applicable for each and every unlawful act in violation of each respective State FCA;

(c) That this Court award such interest as is available pursuant to the FCA;

(d) That in the event the United States intervenes in this action and takes over its prosecution, the Relator be awarded an amount for bringing this action on behalf of the United States of at least 15% but not more than 25% of the proceeds paid to the United States resulting from the trial or settlement of the claim, pursuant to §3730(d)(1) of the FCA;

(e) That in the event the United States and State Plaintiffs do not intervene in this action, the Relator be awarded an amount for bringing this action for the United States of at least 25% but not more than 30% of the proceeds paid to the

United States resulting from the trial or settlement of the claim, pursuant to §3730(d)(2) of the FCA;

(f) That this Court award reasonable attorneys' fees, costs and expenses to the Relator, which were necessarily incurred in bringing and prosecuting this case, pursuant to §3730(d)(1) or (2) of the FCA ; and

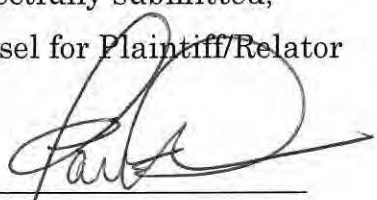
(g) That this Court award such other relief as it deems just, necessary and fair.

JURY DEMAND

Relators requests a trial by jury of all issues so triable.

DATED: June 8, 2017

Respectfully submitted,
Counsel for Plaintiff/Relator



Marc M. Orlow, Esquire
Ross Begelman, Esquire

CERTIFICATION OF SERVICE

Marc Orlow, Esquire, of full age, hereby certify that on June 8, 2017, I filed Relator's Motion to File a Fourth Amended Qui Tam Complaint, Proposed Form of Order in Support of Motion and Relator's Fourth Amended Qui Tam Complaint attached to the Motion to be Filed upon Court's approval in the United States District Court for the Eastern District of Pennsylvania and caused it to be served upon:

Colin Cherico, Esq.
Assistant U.S. Attorney
U.S. Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106

Augustine Ripa, Esq.
U.S. Department of Justice
601 D Street, N.W.
Patrick Henry Builiding, Room 1209
Washington, DC 20004

Attached Service List of State Plaintiffs

by Certified Return Receipt Requested to the above listed people.

I certify that the foregoing statements made by me are true. I am aware if any of the foregoing statements made by me are wilfully false, I am subject to punishment.

BEGELMAN & , ORLOW

By: _____
Marc Orlow, Esquire

Date: June 8, 2017

List of Exhibits for Fourth Amended Complaint

Exhibit A	FDA Label
Exhibit B	Questcor/Nasdaq March 2011
Exhibit C	BROD Plan
Exhibit D	Questcor Power Point
Exhibit E	Achtar Speaker Training
Exhibit F	Questcor Employee Comparative Study
Exhibit G	MIRF
Exhibit H	Referral Form
Exhibit I	New Referral Form
Exhibit J	Abstract-AAN Meeting
Exhibit K	Provider Profile
Exhibit L	List of Speakers
Exhibit M	Stabile Text Message
Exhibit N	Free Vial E-Mail Re: Katz
Exhibit O	2013 Closed Sales Analysis
Exhibit P	2014 Closed Sales Analysis

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Exhibit J	Abstract-AAN Meeting
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EXHIBIT A

These highlights do not include all the information needed to use H.P. Acthar Gel safely and effectively. See full prescribing information for H.P. Acthar Gel.

H.P. Acthar Gel (repository corticotropin injection) [illegible] GEL for INTRAMUSCULAR or SUBCUTANEOUS use
Initial U.S. Approval: 1952

---RECENT MAJOR CHANGES---

Indications and Usage, (1)	10/10
Dosage and Administration, (2)	10/10
Contraindications, Infantile Spasms (4)	10/10
Warnings and Precautions (5)	10/10

---INDICATIONS AND USAGE---

H.P. Acthar Gel is an adrenocorticotropic hormone (ACTH) analogue indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. (1.1)
H.P. Acthar Gel is indicated for the treatment of exacerbations of multiple sclerosis in adults. (1.2)
H.P. Acthar Gel may be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state. (1.3 to 1.9)

---DOSAGE AND ADMINISTRATION---

In the treatment of infantile spasms, the recommended dose is 150 U/m² divided into twice daily intramuscular injections of 75 U/m². After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period. (2.1)
In the treatment of acute exacerbations of multiple sclerosis, daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks may be administered. It may be necessary to taper the dose. (2.2)
In the treatment of other disorders and diseases, dosing will need to be individualized depending on the disease under treatment and the medical condition of the patient. It may be necessary to taper the dose. (2.3)

---DOSAGE FORMS AND STRENGTHS---

5 mL multi-dose vial containing 80 USP units per mL (3)

---CONTRAINDICATIONS---

H.P. Acthar Gel should never be given intravenously.
H.P. Acthar Gel is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin.
Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of H.P. Acthar Gel.
H.P. Acthar Gel is contraindicated in children under 2 years of age with suspected congenital infections. (4)
Treatment of conditions listed within the INDICATIONS section is contraindicated when they are accompanied by primary adrenocortical insufficiency or adrenocortical hyperfunction. (4)

---WARNINGS AND PRECAUTIONS---

- Infections: Increased susceptibility to new infection and increased risk of exacerbation, dissemination or reactivation of latent infections. Signs and symptoms of infection may be masked. (5.1)
- Adrenal Insufficiency after Prolonged Therapy: Monitor for effects of hypothalamic-pituitary-axis suppression after stopping treatment. (5.2)
- Cushing's Syndrome [illegible] after prolonged therapy. Monitor for signs and symptoms. (5.2)
- Elevated Blood Pressure, Salt and Water Retention and Hypokalemia: Monitor blood pressure and sodium and potassium levels. (5.3)
- Vaccination: Do not administer live or attenuated vaccines to patients on immunosuppressive doses. (5.4)
- Masking of Symptoms of Other Underlying Disease/Disorders. Monitor patients for signs of other underlying disease/disorders that may be masked. (5.5)
- Gastrointestinal Perforation and Bleeding: There is a risk for gastric ulcers and bleeding. There is an increased risk of perforation in patients with certain GI disorders. Signs and symptoms may be masked. Monitor for signs of perforation and bleeding. (5.6)
- Behavioral and Mood Disturbances: May include euphoria, insomnia, mood swings, personality changes, severe depression and psychosis. Existing conditions may be aggravated. (5.7)
- Comorbid Diseases: Symptoms of diabetes and myasthenia gravis may be worsened with treatment (5.8)
- Ophthalmic Effects: Monitor for cataracts, infections and glaucoma. (5.9)
- Immunogenicity Potential: Neutralizing antibodies with chronic administration may lead to a loss endogenous ACTH activity. (5.10)
- Use in Patients with Hypothyroidism or Liver Cirrhosis: May result in an enhanced effect. (5.11)
- Negative Effects on Growth and Physical Development: Monitor pediatric patients on long term therapy. (5.12)
- Decrease in Bone Density: Monitor for osteoporosis in patients on long term therapy. (5.13)
- Use in Pregnancy: Embryocidal effect. Apprise women of potential harm to the fetus. (5.14)

---ADVERSE REACTIONS---

- Common adverse reactions for H.P. Acthar Gel are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain. (6)
- Specific adverse reactions resulting from drug use in children under 2 years of age are increased risk of infections, hypertension, irritability, Cushingoid symptoms, cardiac hypertrophy and weight gain. (6.1.1)

To report SUSPECTED ADVERSE REACTIONS, contact Questcor Pharmaceuticals, Inc. at (800) 44[illegible] or (510) 400-0700 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---DRUG INTERACTIONS---

- H.P. Acthar Gel may accentuate the electrolyte loss associated with diuretic therapy. (7)

---USE IN SPECIFIC POPULATIONS---

- Pregnancy: H.P. Acthar Gel has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (8.1)
- Pediatric Use: Prolonged use of H.P. Acthar Gel in children may inhibit skeletal growth. If use is necessary, it should be given intermittently with careful observation. (5.12 and 8.3)

See 17 for Patient Counseling Information and FDA-approved Medication Guide

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FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

1 INDICATIONS AND USAGE

1.1 Infantile spasms:

H.P. Acthar Gel (repository corticotropin injection) is indicated [illegible] therapy for the treatment of infantile spasms in infants and children under 2 years of age.

1.2 Multiple Sclerosis:

H.P. Acthar Gel (repository corticotropin injection) is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

1.3 Rheumatic Disorders:

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis.

1.4 Collagen Diseases:

During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

1.5 Dermatologic Diseases:

Severe erythema multiforme, Stevens-Johnson syndrome.

1.6 Allergic States:

Serum sickness.

1.7 Ophthalmic Diseases:

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation.

1.8 Respiratory Diseases:

Symptomatic sarcoidosis.

1.9 Edematous State:

To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

2 DOSAGE AND ADMINISTRATION

2.1 Specific Recommended Dosage Regimen for Infantile Spasms in Infants and Children Under 2 Years of Age

In the treatment of infantile spasms, H.P. Acthar Gel must be administered intramuscularly. The recommended regimen is a daily dose of 150 U/m² (divided into twice daily intramuscular injections of 75 U/m²) administered over a 2-week period. Dosing with H.P. Acthar Gel should then be gradually tapered over a 2-week period to avoid adrenal insufficiency. The following is one suggested tapering schedule: 30 U/m² in the morning for 3 days; 15 U/m² in the morning for 3 days; 10 U/m² in the morning for 3 days; and 10 U/m² every other morning for 6-days.

H.P. Acthar Gel is typically dosed based on body surface area (BSA). For calculation of body surface area, use the following formula:

$$BSA(m^2) = \sqrt{\frac{weight\ (kg) \times height\ (cm)}{3600}}$$

.2 Recommended Dosage Regimen for the Treatment of Acute Exacerbations in Adults with Multiple Sclerosis.

he recommended dose is daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks for cute exacerbations.

osage should be individualized according to the medical condition of each patient. Frequency and dose f the drug should be determined by considering the severity of the disease and the initial response of ie patient.

though drug dependence does not occur, sudden withdrawal of H.P. Acthar Gel after prolonged use may ad to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment. It may i necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

3 Recommended Dosage Regimen for Other Indications for Adults and Children Over 2 Years of Age

sage should be individualized according to the disease under treatment and the general medical ndition of each patient. Frequency and dose of the drug should be determined by considering severity the disease and the initial response of the patient.

e usual dose of H.P. Acthar Gel is 40-80 units given intramuscularly or subcutaneously every -72 hours.

hough drug dependence does not occur, sudden withdrawal of H.P. Acthar Gel after prolonged use may d to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment. It may necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

Preparation

. Acthar Gel should be warmed to room temperature before using.

ution should be taken not to over-pressurize the vial prior to withdrawing the product.

DOSAGE FORMS AND STRENGTHS

L multi-dose vial containing 80 USP Units per mL.

CONTRAINDICATIONS

Acthar Gel is contraindicated for intravenous administration.

Acthar Gel is contraindicated where congenital infections are suspected in infants.

Inistration of live or live attenuated vaccines is contraindicated in patients receiving unosuppressive doses of H.P. Acthar Gel.

[illegible] Acthar Gel is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infect ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart fa uncontrolled hyperte[illegible] adrenocortical insufficiency, adrenocortical hyperfunction or sensi to proteins of porcin[illegible]

5 WARNINGS AND PRECAUTIONS

The adverse effects of H.P. Acthar Gel are related primarily to its steroidogenic effects. Not all o adverse events described below have been seen after treatment with H.P. Acthar Gel, but migl expected to occur. [*see Adverse Reactions (6.3)*].

5.1 Infections

H.P. Acthar Gel may increase the risks related to infections with any pathogen, including viral, bact fungal, protozoan or helminthic infections. Patients with latent tuberculosis or tuberculin reactivity sh be observed closely, and if therapy is prolonged, chemoprophylaxis should be instituted.

5.2 Cushing's Syndrome and Adrenal Insufficiency Upon Withdrawal

Treatment with H.P. Acthar Gel can cause hypothalamic-pituitary-axis (HPA) suppression and Cushi syndrome. These conditions should be monitored especially with chronic use.

Suppression of the HPA may occur following prolonged therapy with the potential for adrenal insufficie after withdrawal of the medication. Patients should be monitored for signs of insufficiency such weakness, hyperpigmentation, weight loss, hypotension and abdominal pain.

The symptoms of adrenal insufficiency in infants treated for infantile spasms can be difficult to ident The symptoms are non-specific and may include anorexia, fatigue, lethargy, weakness, excessive wei loss, hypotension and abdominal pain. It is critical that parents and caregivers be made aware of possibility of adrenal insufficiency when discontinuing H.P. Acthar Gel and should be instructed to obse for, and be able to recognize, these symptoms [*see Information for Patients (17)*].

The recovery of the adrenal gland may take from days to months so patients should be protected fr the stress (e.g. trauma or surgery) by the use of corticosteroids during the period of stress.

The adrenal insufficiency may be minimized in adults and infants by tapering of the dose wh discontinuing treatment.

Signs or symptoms of Cushing's syndrome may occur during therapy but generally resolve after thera is stopped. Patients should be monitored for these signs and symptoms such as deposition of adipo tissue in characteristics sites (e.g., moon face, truncal obesity), cutaneous striae, easy bruisabili decreased bone mineralization, weight gain, muscle weakness, hyperglycemia, and hypertension.

5.3 Elevated Blood Pressure, Salt and Water Retention and Hypokalemia

H.P. Acthar Gel can cause elevation of blood pressure, salt and water retention, and increased excretic of potassium and calcium. Dietary salt restriction and potassium supplementation may be necessar Caution should be used in the treatment of patients with hypertension, congestive heart failure, or ren insufficiency.

5.4 Vaccination

Administration of live or live attenuated vaccines is contraindicated in patients receivin Immunosuppressive doses of H.P. Acthar Gel. Killed or inactivated vaccines may be administered; howeve the response to such vaccines can not be predicted. Other immunization procedures should be undertaker with caution in patients who are receiving H.P. Acthar Gel, especially when high doses are administered because of the possible hazards of neurological complications and lack of antibody response.

5.5 Masking Symptoms of Other Diseases

H.P. Acthar Gel often acts by masking symptoms of other diseases/disorders without altering the course of the other disease/disorder. Patients should be monitored carefully during and for a period following discontinuation of therapy for signs of infection, abnormal cardiac function, hypertension, hyperglycemia, change in body weight and fecal blood loss.

5.6 Gastrointestinal Perforation and Bleeding

H.P. Acthar Gel can cause GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Signs of gastrointestinal perforation, such as peritoneal irritation, may be masked by the therapy. Use caution where there is the possibility of impending perforation, abscess or other pyogenic infections, diverticulitis, fresh intestinal anastomoses, and active or latent peptic ulcer.

5.7 Behavioral and Mood Disturbances

Use of H.P. Acthar Gel may be associated with central nervous system effects ranging from euphoria, insomnia, irritability (especially in infants), mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated.

5.8 Comorbid Diseases

Patients with a comorbid disease may have that disease worsened. Caution should be used when prescribing H.P. Acthar Gel in patients with diabetes and myasthenia gravis.

5.9 Ophthalmic Effects

Prolonged use of H.P. Acthar Gel may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves and may enhance the establishment of secondary ocular infections due to fungi and viruses.

5.10 Immunogenicity Potential

H.P. Acthar Gel is immunogenic. Limited available data suggest that a patient may develop antibodies to H.P. Acthar Gel after chronic administration and loss of endogenous ACTH and H.P. Acthar Gel activity. Prolonged administration of H.P. Acthar Gel may increase the risk of hypersensitivity reactions. Sensitivity to porcine protein should be considered before starting therapy and during the course of treatment should symptoms arise.

5.11 Use in Patients with Hypothyroidism or Liver Cirrhosis

There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver.

5.12 Negative Effects on Growth and Physical Development

Long-term use of H.P. Acthar Gel may have negative effects on growth and physical development in children. Changes in appetite are seen with H.P. Acthar Gel therapy, with the effects becoming more frequent as the dose or treatment period increases. These effects are reversible once H.P. Acthar Gel

be carefully monitored.

5.13 Decrease in Bone Density

Decrease in bone formation and an increase in bone [illegible]th through an effect on calcium regulation (i.e. decreasing absorption and increasing excretion) and inhibition of osteoblast function may occur. These, together with a decrease in the protein matrix of the bone (secondary to an increase in protein catabolism) and reduced sex hormone production, may lead to inhibition of bone growth in children and adolescents and to the development of osteoporosis at any age. Special consideration should be given to patients at increased risk of osteoporosis (i.e., postmenopausal women) before initiating therapy, and bone density should be monitored in patients on long term therapy.

5.14 Use in Pregnancy

H.P. Acthar Gel has been shown to have an embryocidal effect. Apprise women of potential harm to the fetus. (*see Use In Specific Populations (8.1)*)

6 ADVERSE REACTIONS

Please refer to *Adverse Reactions in Infants and Children Under 2 Years of Age (Section 6.1.1)* for consideration when treating patients with Infantile Spasms. The adverse reactions presented in Section 6.2 are primarily provided for consideration in use in adults and in children over 2 years of age, but these adverse reactions should also be considered when treating infants and children under 2 years of age.

H.P. Acthar Gel causes the release of endogenous cortisol from the adrenal gland. Therefore all the adverse effects known to occur with elevated cortisol may occur with H.P. Acthar Gel administration as well. Common adverse reactions include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain.

6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in practice.

6.1.1 Adverse Reactions in Infants and Children Under 2 Years of Age

While the types of adverse reactions seen in infants and children under age 2 treated for infantile spasms are similar to those seen in older patients, their frequency and severity may be different due to the very young age of the infant, the underlying disorder, the duration of therapy and the dosage regimen. Below is a summary of adverse reactions specifically tabulated from source data derived from retrospective chart reviews and clinical trials in children under 2 years of age treated for infantile spasms. The number of patients in controlled trials at the recommended dose was too few to provide meaningful incidence rates or to permit a meaningful comparison to the control groups.

TABLE: Incidence (%) of Treatment Emergent Adverse Events Occurring in ≥ 2% of H.P. Acthar Gel (repository corticotropin injection) Infants and Children under 2 years of Age

System Organ Class	Recommended 75 U/m² bid n=122, (%)	150 U/m² qd n=37 (%)
Cardiac disorders		
Cardiac Hypertrophy	3	0
Endocrine disorders		
Cushingoid	3	22
Gastrointestinal disorders		
Constipation	0	5
Diarrhea	3	14
Vomiting	3	5
General disorders and administration site conditions		
Irritability	7	19
Pyrexia	5	8
Infections and infestations		
Infection[1]	20	46
nvestigations		
Weight gain	1	3
letabolism and nutrition disorders		
Increased appetite	0	5
Decreased appetite	3	3
lervous system disorders		
Convulsion[2]	12	3
espiratory, thoracic and mediastinal disorders		
Nasal Congestion	1	5
kin and subcutaneous tissue disorders		
Acne	0	14
Rash	0	8
ascular disorders		
Hypertension	11	19

[1] Specific infections that occurred at ≥2% were candidiasis, otitis media, pneumonia and pper respiratory tract infections. [2] In the treatment of Infantile Spasms, other types of izures/convulsions may occur because some patients with infantile spasms progress to other forms seizures (for example, Lennox-Gastaut Syndrome). Additionally the spasms sometimes mask other izures and once the spasms resolve after treatment, the other seizures may become visible.

se adverse reactions may also be seen in adults and children over 2 years of age when treated for er purposes and with different doses and regimens.

6.2 Postmarketing Experience

The following adverse reac[illegible] associated with the use of H.P. Acthar Gel have been identified postmarketing exp[illegible]. Acthar Gel. Only adverse events that are not listed above as a events reported from retro[illegible]ctive chart reviews and non-sponsor conducted clinical trials and not discussed elsewhere in labeling, are listed in this section. Because the adverse reactions are re voluntarily from a population of uncertain size, it is not always possible to estimate their freque establish a causal relationship to use with H.P. Acthar Gel. Events are categorized by system organ Unless otherwise noted these adverse events have been reported in infants, children and adults.

6.2.1 Allergic Reactions

Allergic responses have presented as dizziness, nausea and shock (adults only).

6.2.2 Cardiovascular

Necrotizing angiitis (adults only) and congestive heart failure.

6.2.3 Dermatologic

Skin thinning (adults only), facial erythema and increased sweating (adults only).

6.2.4 Endocrine

Decreased carbohydrate tolerance (infants only) and hirsutism.

6.2.5 Gastrointestinal

Pancreatitis (adults only), abdominal distention and ulcerative esophagitis.

6.2.6 Metabolic

Hypokalemic alkalosis (infants only).

6.2.7 Musculoskeletal

Muscle weakness and vertebral compression fractures (infants only).

6.2.8 Neurological

Headache (adults only), vertigo (adults only), subdural hematoma, intracranial hemorrhage (adults o and reversible brain shrinkage (usually secondary to hypertension) (infants only).

6.3 Possible Additional Steroidogenic Effects

Based on steroidogenic effects of H.P. Acthar Gel certain adverse events may be expected due to pharmacological effects of corticosteroids. The adverse events that may occur but have not been repor for H.P. Acthar Gel are:

6.3.1 Dermatologic

Impaired wound healing, abscess, petechiae and ecchymoses, and suppression of skin test reaction.

6.3.2 Endocrine

Menstrual irregularities.

6.3.3 Metabolic

Negative nitrogen balance due to protein catabolism.

6.3.4 Musculoskeletal

Loss of muscle mass and aseptic necrosis of femoral and humeral heads.

6.3.5 Neurological

Increased intracranial pressure with papilledema, (pseudo-tumor cerebri) usually after treatment, ar subdural effusion.

6.3.6 Ophthalmic

Exophthalmos.

7 DRUG INTERACTIONS

Formal drug-drug interaction studies have not been performed.

H.P. Acthar Gel may accentuate the electrolyte loss associated with diuretic therapy.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Class C: H.P. Acthar Gel has been shown to have an embryocidal effect. There are no adequat and well-controlled studies in pregnant women. H.P. Acthar Gel should be used during pregnancy only i the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in humar milk and because of the potential for serious adverse reactions in nursing infants from H.P. Acthar Gel, when treating a nursing mother, a decision should be made whether to discontinue nursing or to discontinue the drug, considering the risk and benefit to the mother.

8.4 Pediatric Use

H.P. Acthar Gel is indicated as monotherapy for the treatment of infantile spasms in infants and children less than 2 years of age. Both serious and other adverse reactions in this population are discussed in Warnings and Adverse Reactions in Infants and Children Under 2 Years of Age [*see Sections 5 and 6.1.1*].

The efficacy of H.P. Acthar Gel for the treatment of infantile spasms in infants and children less than 2 years of age was evaluated in a randomized, single blinded (video EEG interpreter blinded) clinical trial and an additional active control supportive trial [*see Clinical Studies (14)*]. A responding patient was defined as having both complete cessation of spasms and elimination of hypsarrhythmia.

Safety in the pediatric population for infantile spasms was evaluated by retrospective chart reviews and data from non-sponsor conducted clinical trials [*see Adverse Reactions (6.1.1)*]. While the types of adverse reactions seen in infants and children under 2 years of age treated for infantile spasms are similar to those seen in older patients, their frequency and severity may be different due to the very young age of the infant, the underlying disorder, the duration of therapy and the dosage regimen. Effects on growth are of particular concern [*see Warnings and Precautions (5.12)*]. Serious adverse reactions observed in adults may also occur in children [*see Warnings and Precautions (5)*].

10 OVERDOSAGE

While chronic exposure to H.P. Acthar Gel at high doses can be associated with a variety of potential serious adverse effects, it is not expected that a single high dose, or even several large doses, has the

possibility for serious adverse effects compared to a standard dose. There have been no reports of death or acute overdose symptoms from H.P. Acthar Gel in clinical studies or in the published literature.

The intramuscular route of administration makes it unlikely that [illegible] ertent acute overdose will occur. The typical daily dose of H.P. Acthar Gel to treat an infan[illegible] BSA of 0.4 m^2 would be 60 U/day. Using the 1-cc syringe supplied with H.P. Acthar Gel, the maximum amount that can be injected is 80 U/injection, which is a well-tolerated single dose.

11 DESCRIPTION

H.P. Acthar Gel is a highly purified sterile preparation of the adrenocorticotropic hormone in 16% gelatin to provide a prolonged release after intramuscular or subcutaneous injection. Also contains 0.5% phenol, not more than 0.1% cysteine (added), sodium hydroxide and/or acetic acid to adjust pH and water for injection.

ACTH is a 39 amino acid peptide with the following chemical formula:

H-	Ser-	Tyr-	Ser-	Met-	Glu-	His-	Phe-	Arg-	Trp-	Gly-
	1	2	3	4	5	6	7	8	9	10
	Lys-	Pro-	Val-	Gly-	Lys-	Lys-	Arg-	Arg-	Pro-	Val-
	11	12	13	14	15	16	17	18	19	20
	Lys-	Val-	Tyr-	Pro-	Asp-	Gly-	Ala-	Glu-	Asp-	Gln-
	21	22	23	24	25	26	27	28	29	30
	Leu-	Ala-	Glu-	Ala-	Phe-	Pro-	Leu-	Glu-	Phe-	OH
	31	32	33	34	35	36	37	38	39	

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of H.P. Acthar Gel in the treatment of infantile spasms is unknown.

H.P. Acthar Gel and endogenous ACTH stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. Prolonged administration of large doses of H.P. Acthar Gel induces hyperplasia and hypertrophy of the adrenal cortex and continuous high output of cortisol, corticosterone and weak androgens. The release of endogenous ACTH is under the influence of the nervous system via the regulatory hormone released from the hypothalamus and by a negative corticosteroid feedback mechanism. Elevated plasma cortisol suppresses ACTH release.

H.P. Acthar Gel is also reported to bind to melanocortin receptors.

The trophic effects of endogenous ACTH and H.P. Acthar Gel on the adrenal cortex are not well understood beyond the fact that they appear to be mediated by cyclic AMP.

ACTH rapidly disappears from the circulation following its intravenous administration; in people, the plasma half-life is about 15 minutes. The pharmacokinetics of H.P. Acthar Gel have not been adequately characterized.

The maximal effects of a trophic hormone on a target organ are achieved when optimal amounts of hormone are acting continuously. Thus, a fixed dose of H.P. Acthar Gel will demonstrate a linear increase in adrenocortical secretion with increasing duration for the infusion.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Adequate and well-controlled studies have not been done in animals. Human use has not been associated with an increase in malignant disease. [*see Warnings and Precautions (5.14) and Use in Specific Populations (8.1)*].

14 CLINICAL STUDIES

The effectiveness of H.P. Acthar Gel as a treatment for infantile spasms was demonstrated in a single blinded (video EEG interpreter blinded) clinical trial in which patients were randomized to receive either a 2 week course of treatment with H.P. Acthar Gel (75 U/m^2 intramuscular twice daily) or prednisone (1 mg/kg by mouth twice daily). The primary outcome was a comparison of the number of patients in each group who were treatment responders, defined as a patient having complete suppression of both clinical spasms and hypsarrhythmia on a full sleep cycle video EEG performed 2 weeks following treatment initiation, rated by an investigator blinded to treatment. Thirteen of 15 patients (86.7%) responded to H.P. Acthar Gel as compared to 4 of 14 patients (28.6%) given prednisone ($p<0.002$). The 2-week treatment was followed by a 2-week period of taper. Nonresponders to the prednisone treatment were eligible to receive H.P. Acthar Gel treatment. Seven of 8 patients (87.5%) responded to H.P. Acthar Gel after not responding to prednisone. Similarly, the 2 nonresponder patients from the H.P. Acthar Gel treatment were eligible to receive treatment with prednisone. One of the 2 patients (50%) responded to the prednisone treatment after not responding to H.P. Acthar Gel.

A supportive single-blind, randomized clinical trial comparing high-dose, long-duration treatment (150 U/m^2 once daily for 3 weeks, n=30) of H.P. Acthar Gel with low-dose, short-duration treatment (20 U once daily for 2 weeks, n=29) for the treatment of infantile spasms was also evaluated in infants and children less than 2 years of age. Nonresponders (defined as in the previously described study) in the low-dose group received a dose escalation at 2 weeks to 30 U once daily. Nominal statistical superiority of the high dose treatment, as compared to the low dose treatment, was observed for cessation of spasms but not for the resolution of hypsarrhythmia.

16 HOW SUPPLIED / STORAGE AND HANDLING

H.P. Acthar Gel (repository corticotropin injection) is supplied as 5 mL multi-dose vial (63004-7731-1) containing 80 USP Units per mL. H.P. Acthar Gel (repository corticotropin injection) should be warmed to room temperature before using. Do not over pressurize the vial prior to withdrawing the product.

Store H.P. Acthar Gel (repository corticotropin injection) under refrigeration between 2°-8°C (36°-46°F). Product is stable for the period indicated on the label when stored under the conditions described.

17 PATIENT COUNSELING INFORMATION

Prescribers of patients with infantile spasms should be informed of the availability of a Medication Guide, and they should be instructed to read the Medication Guide prior to administering H.P. Acthar Gel. Patients should be instructed to take H.P. Acthar Gel only as prescribed. They should not stop treatment suddenly unless instructed by their physician to do so.

Patients, their caregivers and families should be advised as to the importance of the need for c[illegible] monitoring while on [illegible]duration from H.P. Acthar Gel treatment and the importance of not mi[illegible] and scheduled dos[illegible]nts.

Patients, their caregivers and families should be advised that if the patient develops an infect[illegible] fever they should contact their physician. They should be educated that a fever may not necessar[illegible] present during infection. The patient should also try to limit contact with other people with infectio[illegible] minimize the risk of infection while taking H.P. Acthar Gel. [*see Warnings and Precautions (5.1[illegible] Adverse Reactions (6.1.1)*].

Patients, their caregivers and families should be advised that if the patient experiences an increa[illegible] blood pressure they should contact their physician. [*see Warnings and Precautions (5.3) and Ad[illegible] Reactions (6.1.1)*].

Patients, their caregivers and families should be advised that if the patient or the caregiver notices t[illegible] or a change in color of the patient's stool they should contact their physician. [*see Warnings[illegible] Precautions (5.6)*].

Caregivers and families of infants and children treated with H.P. Acthar Gel should be informed tha[illegible] patient may show signs of irritability and sleep disturbances. These effects are reversible once H.P. Ac[illegible] Gel therapy is stopped. [*see Warnings and Precautions (5.7) and Adverse Reactions (6.1.1)*].

Patients, their caregivers and families should be advised that changes in appetite, most often loa[illegible] to weight gain, are seen with H.P. Acthar Gel therapy, becoming more frequent as the dose or treatm[illegible] period increases. These effects are reversible once H.P. Acthar Gel therapy is stopped. [*see Warnings[illegible] Precautions (5.12) and Adverse Reactions (6.1.1)*].

Patients, their caregivers and families should be advised that the patient may be monitored for signs[illegible] adrenal insufficiency such as weakness, fatigue, lethargy, anorexia, weight loss, hypotension, abdomi[illegible] pain or hyperpigmentation (adults only) after treatment has stopped. Since the recovery of the adre[illegible] gland varies from days to months, patients may need to be protected from the stress of trauma or surg[illegible] by the use of corticosteroids during the period of stress. [*see Warnings and Precautions (5.2)*].

Patients should be advised not to be vaccinated with live or live attenuated vaccines during treatm[illegible] with H.P. Acthar Gel. Additionally, other immunization procedures in patients or in family members w[illegible] will be in contact with the patient should be undertaken with caution while the patient is tak[illegible] H.P. Acthar Gel. [*see Warnings and Precautions (5.4)*].

Patients, their caregivers and families should be advised that prolonged use of H.P. Acthar Gel in child[illegible] may result in Cushing's syndrome and associated adverse reactions, may inhibit skeletal growth, a[illegible] may cause osteoporosis and decreased bone density. If prolonged use is necessary, H.P. Acthar Gel shou[illegible] be given intermittently along with careful observation. [*see Warnings and Precautions (5.2), (5.12), a[illegible] (5.13) and Adverse Reactions (6.1.1)*].

Patients, their caregivers and families should be informed that H.P. Acthar Gel may mask symptoms[illegible] other diseases/disorders without altering the course of the other disease/disorder. The patient will ne[illegible] to be monitored carefully during and for a period following discontinuation of therapy for signs of infectio[illegible] abnormal cardiac function, hypertension, hyperglycemia, change in body weight, and fecal blood los[illegible] [*see Warnings and Precautions (5.5)*].

In the treatment of Infantile Spasms, other types of seizures may occur because some patients wi[illegible] Infantile spasms progress to other forms of seizures (for example, Lennox-Gastaut Syndrome). Additiona[illegible] the spasms sometimes mask other seizures and once the spasms resolve after treatment with H.P. Acth[illegible] Gel, the other seizures may become visible. Parents and caregivers should inform their physician of an[illegible] new onset of seizures so that appropriate management can then be instituted. [*see Adverse Reaction[illegible] (6.1.1)*].

H.P. Acthar® Gel
(repository corticotropin injection)
Manufactured for Questcor Pharmaceuticals, Inc.

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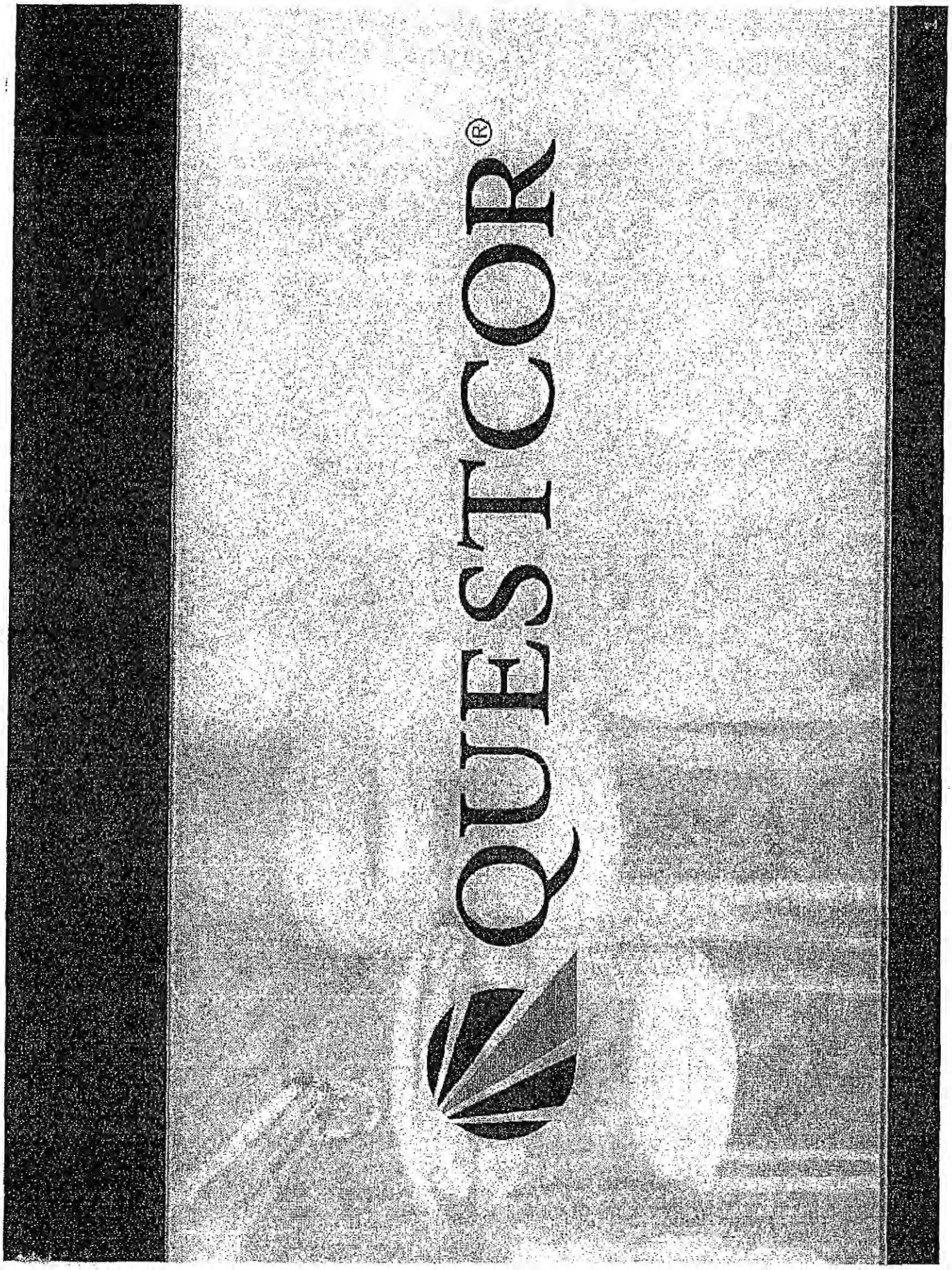
EXHIBIT B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